Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
May 7, 2018	
Tisagenlecleucel ***(Kymriah—Novartis)*** **Agent receives second FDA approval to refractory or relapsed large B-cell lymphoma**	FDA has approved tisagenlecleucel suspension for I.V. infusion for its second indication—treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. It is not indicated for treatment of patients with primary central nervous system lymphoma. The agent was the first chimeric antigen receptor T cell (CAR-T) therapy to receive regulatory approval in August 2017 to treat patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Tisagenlecleucel is now the only CAR-T cell therapy to receive FDA approval for two distinct indications in non-Hodgkin lymphoma (NHL) and B-cell ALL

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http://aphanet.org/supplemental-approvals/agent-receives-second-fda-approval-refractory-or-relapsed-large-b-cell